2095

Bimekizumab response through three years of treatment in patients with moderate to severe plaque psoriasis who responded after 16 weeks: Results from the open-label extension of BE RADIANT

Richard G. Langley,[1] Pablo Fernandez-Peñas,[2] James Krueger,[3] Ulrich Mrowietz,[4] Carle Paul,[5] Maggie Wang,[6] Bengt Hoepken,[7] Markus Kaspar,[7] Susanne Wiegratz,[7] Valerie Ciaravino,[8] Andreas Pinter[9]

Objective

To assess maintenance of clinical and health-related quality of life (HRQoL) responses through 144 weeks of treatment with bimekizumab (BKZ) in patients with moderate to severe plaque psoriasis who had an initial efficacy response after 16 weeks.

Background

- Real-world studies have shown that only 53–58% of patients with plaque psoriasis remain on a biologic therapy for ≥3 years.[1]
- Given the chronic nature of psoriasis, it is therefore important to evaluate long-term treatment efficacy.
- BKZ, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A,[2] has demonstrated rapid and superior efficacy in the treatment of patients with moderate to severe plaque psoriasis in head-to-head studies versus ustekinumab, adalimumab and secukinumab, with established long-term durability of response.[3–7]
- Maintenance of response over 96 weeks of BE RADIANT has been reported previously.[8] Here, maintenance of efficacy and HRQoL responses over 144 weeks of BE RADIANT, to the end of the main open-label extension (OLE) period, are presented.

Methods

- In BE RADIANT, patients initially randomised to BKZ 320 mg every 4 weeks (Q4W) either continued Q4W dosing or switched to BKZ Q8W at Week 16. Upon entering the OLE at Week 48, patients received BKZ Q4W or Q8W (**Figure 1**).[6]
- Maintenance of Psoriasis Area and Severity Index (PASI) 90/100 (≥90%/100% improvement from baseline in PASI) and Dermatology Life Quality Index (DLQI) 0/1 responses (no effect of skin disease on patient's life)[9] to Week 144 was assessed for Week 16 responders.
- Data are reported for all BKZ-randomised patients who entered the OLE (BKZ Total), and for the subset of patients receiving BKZ Q4W/Q8W/Q8W (initial/maintenance/OLE) dosing.
- Missing data were imputed using modified non-responder imputation (mNRI).
  - Patients who discontinued treatment due to lack of efficacy or treatment-related adverse events were considered non-responders; multiple imputation was used for all other missing data.
- Non-responder imputation (NRI) and observed case (OC) data are reported in **Table 2**.

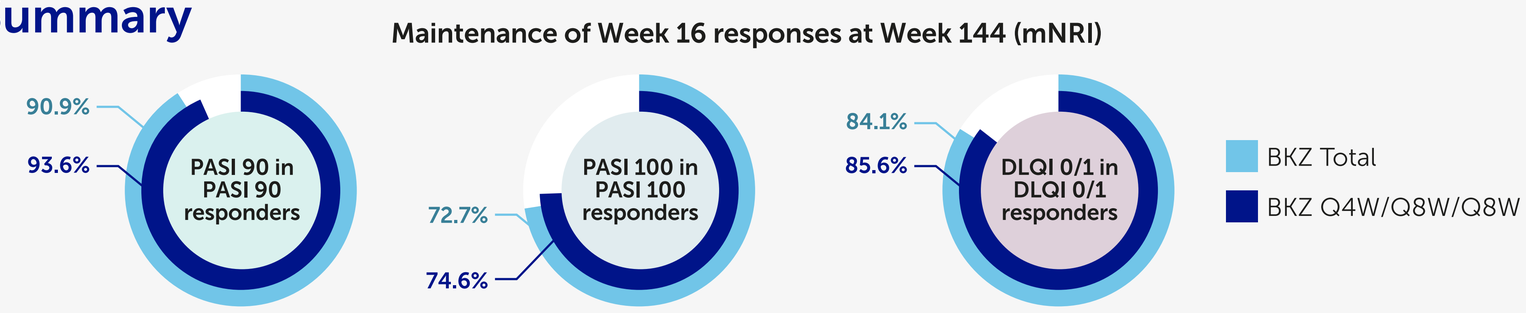
Results

- 373 patients were randomised at baseline to BKZ; baseline characteristics are presented in **Table 1**.
- High levels of response were observed at Week 16 (**Figures 2A–C**); 302 Week 16 PASI 90 responders, 216 Week 16 PASI 100 responders and 278 Week 16 DLQI 0/1 responders entered the OLE.
- 90.9% of Week 16 PASI 90 responders, 72.7% of Week 16 PASI 100 responders and 84.1% of Week 16 DLQI 0/1 responders maintained their response at Year 3 (Week 144) (**Figures 2A–C**).
- Similar patterns were seen for patients who received BKZ dosed Q4W/Q8W/Q8W (**Figures 2A–C**).

Conclusions

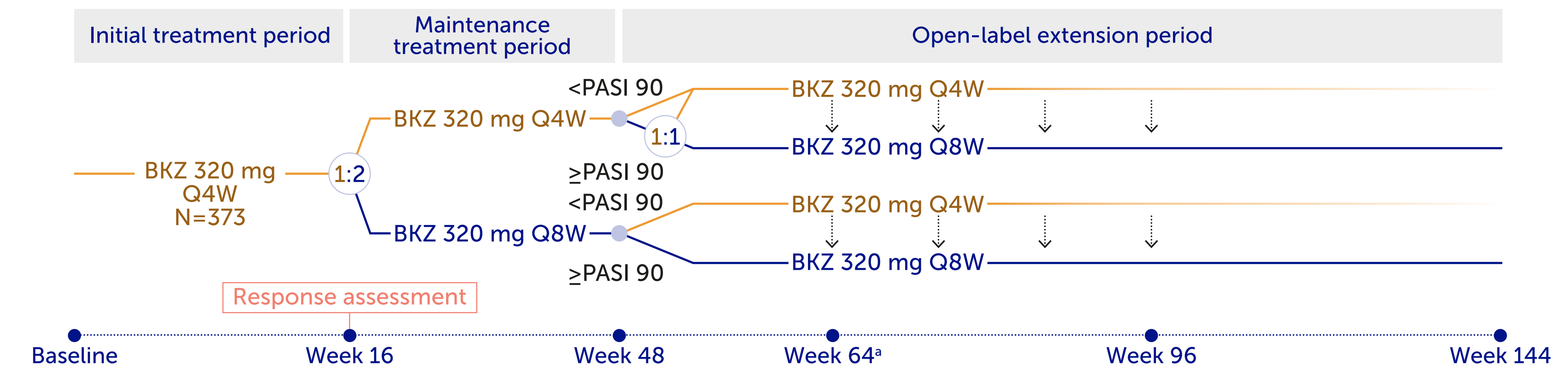
The vast majority of patients maintained Week 16 efficacy and HRQoL responses through 3 years of BKZ treatment, including patients who received BKZ 320 mg Q4W/Q8W/Q8W.

Summary



BKZ provided **long-term maintenance of efficacy** and **health-related quality of life** outcomes in patients with moderate to severe plaque psoriasis

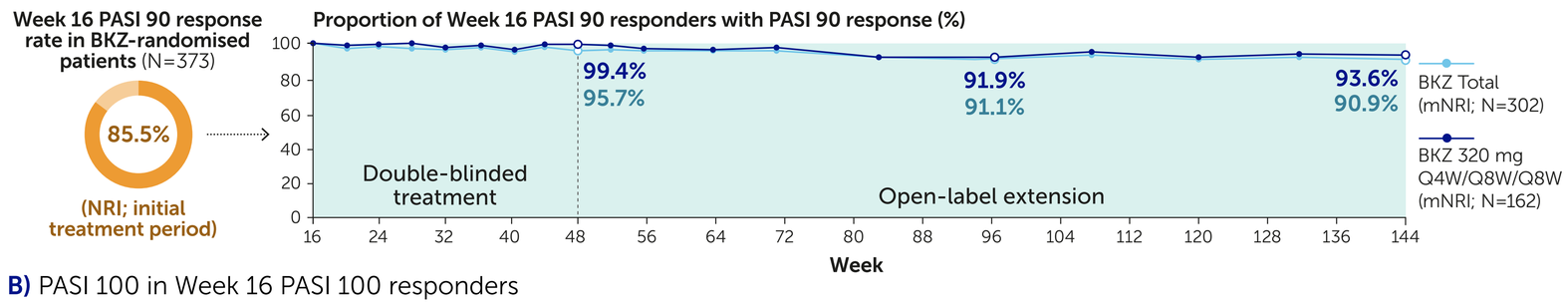
Figure 1 Included patients



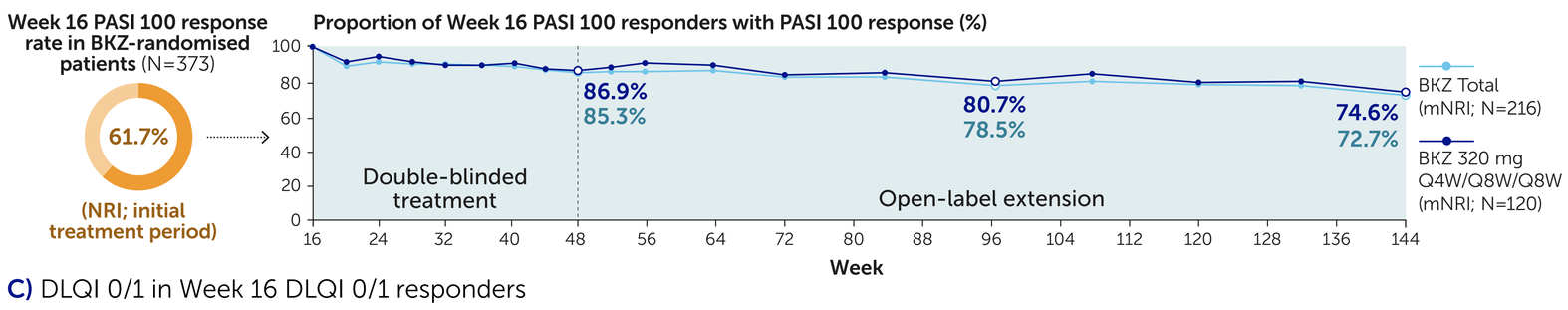
[a]Following a protocol amendment, all patients receiving BKZ 320 mg Q4W in the OLE period switched to BKZ 320 mg Q8W at the next scheduled clinic visit at or after Week 64. The BE RADIANT trial also included SEC-randomised patients, who are not shown here.

Figure 2 Maintenance of efficacy over 3 years in patients with a Week 16 response who entered the OLE (mNRI)

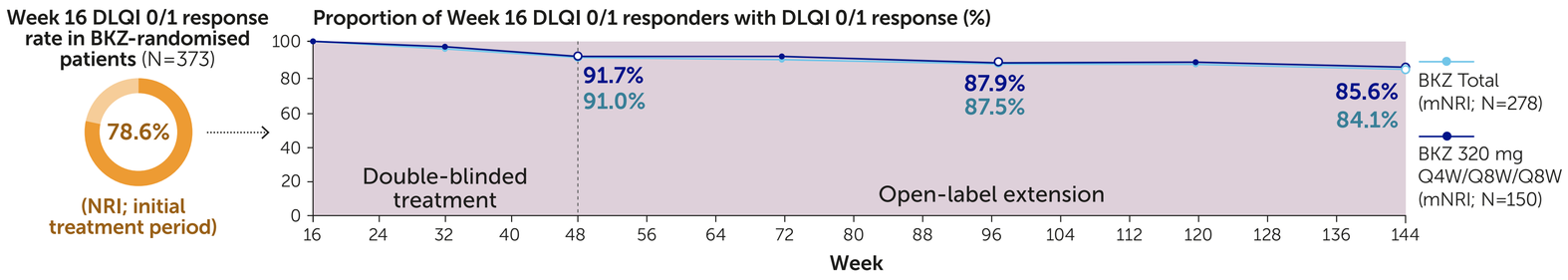
A) PASI 90 in Week 16 PASI 90 responders



B) PASI 100 in Week 16 PASI 100 responders



C) DLQI 0/1 in Week 16 DLQI 0/1 responders



Week 16 responses are shown for all patients randomised to BKZ 320 mg Q4W at baseline. Data through Weeks 16–144 are reported for all patients who were treated continuously with BKZ through the initial and maintenance periods, achieved the efficacy response of interest at Week 16 and entered the OLE.

Table 1 Baseline characteristics

	Week 16 PASI 90 responders BKZ Total (N=302)	Week 16 PASI 100 responders BKZ Total (N=216)	Week 16 DLQI 0/1 responders BKZ Total (N=278)
Age (years), mean ± SD	45.0 ± 13.9	45.6 ± 13.8	45.3 ± 13.7
Male, n (%)	201 (66.6)	145 (67.1)	194 (69.8)
Weight (kg), mean ± SD	89.3 ± 20.7	88.3 ± 20.4	90.2 ± 21.3
Duration of psoriasis (years), mean ± SD	17.8 ± 12.8	18.7 ± 13.3	18.8 ± 13.0
PASI, mean ± SD	20.3 ± 7.6	19.9 ± 7.4	20.5 ± 7.9
BSA (%), mean ± SD	25.1 ± 15.9	23.8 ± 14.9	25.6 ± 16.1
DLQI total score, mean ± SD	11.1 ± 6.6	11.1 ± 6.8	10.3 ± 6.6
Any prior systemic therapy, n (%)	215 (71.2)	153 (70.8)	198 (71.2)
Prior biologic therapy, n (%)	102 (33.8)	72 (33.3)	94 (33.8)

Data are reported for all patients who were treated continuously with BKZ through the initial and maintenance periods, achieved the efficacy response of interest at Week 16 and entered the OLE.

Table 2 Summary of efficacy outcomes (NRI and OC)

	Week 16 PASI 90 responders			
	NRI, n (%)	OC, n/N (%)	NRI, n (%)	OC, n/N (%)
	BKZ Total N=302		BKZ 320 mg Q4W/Q8W/Q8W N=162	
PASI 90 Response				
Year 1 (Week 48)	282 (93.4)	282/295 (95.6)	156 (96.3)	156/157 (99.4)
Year 2 (Week 96)	258 (85.4)	258/275 (93.8)	141 (87.0)	141/149 (94.6)
Year 3 (Week 144)	240 (79.5)	240/252 (95.2)	131 (80.9)	131/134 (97.8)
	Week 16 PASI 100 responders			
	BKZ Total N=216		BKZ 320 mg Q4W/Q8W/Q8W N=120	
PASI 100 Response				
Year 1 (Week 48)	182 (84.3)	182/211 (86.3)	103 (85.8)	103/117 (88.0)
Year 2 (Week 96)	162 (75.0)	162/195 (83.1)	93 (77.5)	93/110 (84.5)
Year 3 (Week 144)	144 (66.7)	144/179 (80.4)	81 (67.5)	81/99 (81.8)
	Week 16 DLQI 0/1 responders			
	BKZ Total N=278		BKZ 320 mg Q4W/Q8W/Q8W N=150	
DLQI 0/1 Response				
Year 1 (Week 48)	247 (88.8)	247/271 (91.1)	133 (88.7)	133/145 (91.7)
Year 2 (Week 96)	230 (82.7)	230/252 (91.3)	125 (83.3)	125/137 (91.2)
Year 3 (Week 144)	206 (74.1)	206/232 (88.8)	111 (74.0)	111/124 (89.5)

Data are reported for all patients who were treated continuously with BKZ through the initial and maintenance periods, achieved the efficacy response of interest at Week 16 and entered the OLE.

BKZ: bimekizumab; **BSA:** body surface area; **DLQI:** Dermatology Life Quality Index; **mNRI:** modified non-responder imputation; **NRI:** non-responder imputation; **OC:** observed case; **OLE:** open-label extension; **PASI 90/100:** ≥90%/100% improvement from baseline in Psoriasis Area and Severity Index; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks; **SD:** standard deviation; **SEC:** secukinumab.

Institutions: [1]Division of Clinical Dermatology and Cutaneous Science, Dalhousie University, Halifax, Nova Scotia, Canada; [2]The University of Sydney, Westmead Hospital, Department of Dermatology, Westmead, New South Wales, Australia; [3]Centre for Clinical and Translational Science, The Rockefeller University, New York, New York, USA; [4]Psoriasis-Center, Department of Dermatology, University Medical Center Schleswig-Holstein, Campus Kiel, Germany; [5]Department of Dermatology and Allergology, Toulouse University and CHU, Toulouse, France; [6]UCB Pharma, Morrisville, North Carolina, USA; [7]UCB Pharma, Monheim, Germany; [8]UCB Pharma, Colombes, France; [9]Department of Dermatology, Venereology and Allergology, University Hospital Frankfurt, Frankfurt am Main, Germany.

References: [1]Yiu ZZN *et al.* Br J Dermatol 2020;183:294–302; [2]Adams *et al.* Front Immunol 2020;11:1894; [3]Reich K *et al.* Lancet 2021;397:487–98; [4]Gordon KB *et al.* Lancet 2021;397:475–86; [5]Warren RB *et al.* N Engl J Med 2021;385:130–41; [6]Reich K *et al.* N Engl J Med 2021;385:142–52 (NCT03536884); [7]Strober B *et al.* Br J Dermatol 2023;188:749–59, NCT03598790; [8]Warren RB *et al.* Presented at BAD 2022, P85; [9]Hongbo Y *et al.* J Investig Dermatol 2005;4:659–64. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **RGL, PFP, JK, UM, CP, MW, BH, MK, SW, VC, AP;** Drafting of the publication, or revising it critically for important intellectual content: **RGL, PFP, JK, UM, CP, MW, BH, MK, SW, VC, AP;** Final approval of the publication: **RGL, PFP, JK, UM, CP, MW, BH, MK, SW, VC, AP**. **Author Disclosures: RGL:** Served as a principal investigator for AbbVie, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly, Janssen, LEO Pharma, Merck, Novartis, Pfizer and UCB Pharma; served on scientific advisory boards for AbbVie, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly, LEO Pharma, Merck, Novartis, Pfizer and UCB Pharma; provided lectures for AbbVie, Amgen, Celgene, Eli Lilly, Janssen, LEO Pharma, Merck, Novartis and Pfizer. **PFP:** Served on an advisory committee for AbbVie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly, Janssen, LEO Pharma, Merck, MSD, Novartis, Roche, Sanofi and Sun Pharma; educational lectures for AbbVie, Amgen, Avene, Eli Lilly, Galderma, Janssen, La Roche Posay, LEO Pharma, Merck, Novartis, Pfizer, Roche, Sanofi, Schering Plough, Sun Pharma and UCB Pharma; clinical trials for AbbVie, Amgen, Arena, AstraZeneca, Boehringer Ingelheim, Bristol Myers Squibb, CSL, Dermira, Eisai, Eli Lilly, Galderma, GSK, Janssen, Jiangsu Hengrui, Kyowa Hakko Kirin, LEO Pharma, miRagen, Novartis, OncoSec, Pfizer, Regeneron, Roche, Sun Pharma, UCB Pharma and Xoma. **JK:** Grants paid to institution from AbbVie, Akros, Allergan, Amgen, Avillion, Biogen, Boehringer Ingelheim, Botanix, Bristol Myers Squibb, Celgene, Eli Lilly, Exicure, Incyte, Innovaderm, Janssen, LEO Pharma, Novan, Novartis, Paraxel, Pfizer, Regeneron, Sienna, UCB Pharma and Vitae; personal fees from AbbVie, Aclaris, Allergan, Almirall, Amgen, Arena, Aristea, Asana, Aurigne, BiogenIdec, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly, Escalier, Galapagos, LEO Pharma, Menlo, Nimbus, Novartis, Pfizer, Sanofi, Sienna, Sun Pharma, UCB Pharma, Valeant and Ventyx. **UM:** Served as advisor and/or clinical study investigator for, and/or received honoraria and/or grants from AbbVie, Almirall, Aristea, Boehringer Ingelheim, Celgene, Dr. Reddy's Laboratories, Eli Lilly, Foamix, Formycon, Forward Pharma, Janssen, LEO Pharma, Medac, Novartis, Phi-Stone, Pierre Fabre, Sanofi and UCB Pharma. **CP:** Consulting fees and/or grants from AbbVie, Almirall, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly, GSK, Janssen-Cilag, LEO Pharma, Novartis, Pierre Fabre, Pfizer, Sanofi, Regeneron and UCB Pharma. **MW, BH, SW, VC:** Employees and shareholders of UCB Pharma. **MK:** Employees of UCB Pharma. **AP:** Investigator and/or speaker and/or advisor for AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Celgene, Eli Lilly, Galderma, GSK, Hexal, Janssen, LEO Pharma, MC2, Medac, Merck Serono, Mitsubishi Pharma, MSD, Novartis, Pfizer, Regeneron, Roche, Sandoz, Schering-Plough, Tigercat Pharma and UCB Pharma. **Acknowledgements:** This study was funded by UCB Pharma. We thank the patients and their caregivers in addition to the investigators and their teams who contributed to this study. The authors acknowledge Susanne Wiegratz, MSc, UCB Pharma, Monheim, Germany, for publication coordination, Jérémy Lambert, PhD, UCB Pharma, Colombes, France, for critical review, Sana Yaar, PhD, Costello Medical, Manchester, UK for medical writing and editorial assistance and the Creative team, Costello Medical, UK for graphic design assistance. All costs associated with development of this poster were funded by UCB Pharma.

To receive a copy of this poster, scan the QR code or visit: UCBposters.com/WCD2023
Poster ID: 2095
Link expiration: 6 October 2023